

REMARKS

Favorable consideration and allowance are respectfully requested for claims 1-23 based on the following remarks.

The Examiner is thanked for the telephonic interview conducted February 13, 2008, the substance of which is reflected herein. As reflected in the Interview Summary mailed February 19, 2008, an agreement was reached that the withdrawn claims would be rejoined in this application. The undersigned also understood that the Examiner preferred the Applicant's to respond to the Office Action of October 18, 2007 rather than issuing a new Office Action and that an agreement was reached that any subsequent Office Action would be non-final, given that the Office Action of October 18, 2007 did not include an examination of all of the claims, despite the prior amendment to put all of the claims within the elected group.

Thus, rejoinder of any withdrawn claims is respectfully requested. As explained in the previously-filed response, all of the pending claims fall within elected Group II. Accordingly, there is no reason to withdraw any claims on the basis of the original restriction requirement.

Further, with the exception of claims 22 and 23, all of the pending claims are either specific, or at least generic, to the elected species. Accordingly, the withdrawal of claims 3-14 is respectfully traversed and reconsideration of the withdrawal of these claims is respectfully requested. Moreover, the claims directed to the elected species are allowable for at least the reasons articulated below, and accordingly, rejoinder of any remaining withdrawn claims is respectfully requested.

The rejection of claims 1, 2, and 16 under 35 U.S.C. 102(a) as anticipated by WO 03/037379 ("Hasenzahl") is respectfully traversed.

Hasenzahl provides a laundry list of suitable compounds. This list runs on for nearly 4 pages, see pages 13 - 16. There is nothing in reference that would cause the skilled artisan to select faropenem from among the numerous compounds cited therein, as is asserted in the Office Action. Further, the examples in the reference are limited to vitamin E acetate, acetylsalicylic acid and paracetamol. These exemplary compounds are nothing like the penem antibiotics recited in claim 1, much less the faropenem of claim 16. Thus, the reference provides no evidence to substantiate any assertion that combining faropenem with silicon materials might yield any beneficial result.

Further, in order to anticipate, a prior art reference must actually enable the claimed invention. See, e.g., *Elan Pharmaceuticals, Inc. v. Mayo Foundation*, 346 F.3d 1051, 1054-55 (Fed. Cir. 2003) (anticipation requires enablement, whereby the reference "must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation"); *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339 (Fed. Cir. 2000) (a prior art reference that does not enable a person of ordinary skill in the art to practice the claimed invention does not anticipate the patent claims); *Akzo N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1480 (Fed. Cir. 1986) (anticipation requires that the reference publicly discloses all elements of the claimed invention and enables its practice).

In the present instance, the Hasenzahl reference provides little more than an invitation to experiment. Given the unpredictability of the chemical arts, and, in particular, the pharmacological arts, the Hasenzahl reference provides the skilled artisan no assurance that the presently claimed invention might represent any improvement over a formulation of faropenem by itself, or even faropenem with some carrier or adjuvant. As such, based on the limited disclosure of the Hasenzahl reference it cannot be the case that a skilled artisan can be said to have had a reasonable expectation of success in the presently claimed invention.

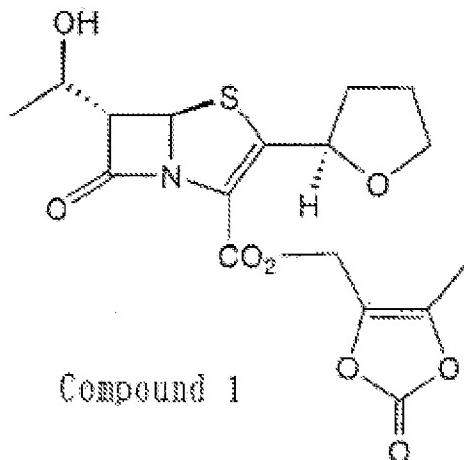
Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

The rejection of claims 1 and 17-19 under 35 U.S.C. 103(a) as obvious over Hasenzahl is respectfully traversed.

As explained above, the Hasenzahl reference does not anticipate the present invention. There is nothing in the cited reference that would cause one of skill in the art to reasonably expect the results achieved by the presently claimed invention. As such, these results are unexpected and unpredictable, and could not have been foreseen based on the cited art.

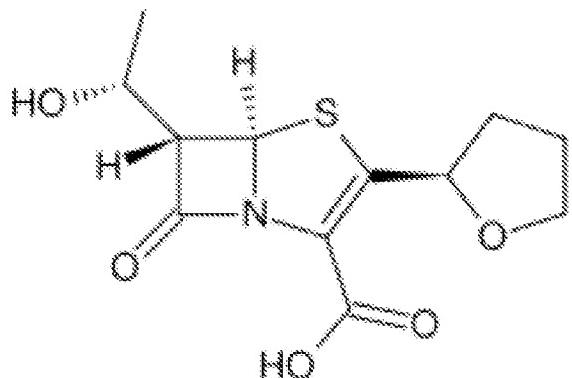
In particular, these results are detailed in the present specification, which describes that faropenem daloxate is susceptible to degradation, see Figure 1 and the related description in paragraphs [0014-0015]. Table 1 shows degradation of faropenem daloxate after just seven days, whereas Table 5 shows that silicate material was effective to preclude such quick degradation, even for the extended period of one year. Hasenzahl does not describe any results with the penem antibiotics of claim 1, or even compounds like the claimed penem antibiotics. Accordingly, the rejection of claim 1 cannot be properly maintained.

Claim 17 is directed to a hard capsule with a penem antibiotic where the penem antibiotic is (5-methyl-2-oxo-1,3-dioxolene-4-yl)methyl (5R,6S)-6-[(R)-1-hydroxyethyl]-7-oxo-3-[(R)-2-tetrahydrofuryl]-4-thia-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylate. As is explained in paragraph [0007] of the specification, this compound is named faropenem daloxate, which has the following structure:



See paragraphs [0007] and [0016].

In contrast, the cited portion of Hasenzahl describes faropenem, which has the following, significantly different, structure:



Thus, the reference does not describe the compound recited in claim 17. Moreover, on the present record, there is nothing that would cause one of skill in the art to disregard the teachings of the reference and try to use the faropenem daloxate compound of recited in claim 17. Thus, claim 17 is not obvious based on the cited reference.

Dependent claims 18 and 19 are nonobvious for at least the reasons cited above. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

The rejection of claims 1, 20, and 21 under 35 U.S.C. 103(a) as obvious over Hasenzahl in view of U.S. Application No. 2003/0124188 (“Burnside”) is respectfully traversed.

First, the secondary reference does not make up for the deficiencies of Hasenzahl which are described above. As such, claim 1 is allowable over the proposed combination of references.

Moreover, claim 20 is directed to a hard capsule in which an inorganic substance is contained with a penem antibiotic filled therein, where the penem antibiotic is a mixture of a penem antibiotic with a functional coating and a penem antibiotic without a functional coating. Claim 21 depends from claim 20 and recites a particular ratio of penem antibiotic with a functional coating to penem antibiotic without a functional coating. Thus, in these claims, the active ingredient is provided in two forms, one form with a coating and one form without a coating.

Hasenzahl is silent as to any arrangement where a penem antibiotic is provided as a mixture where a portion of the antibiotic has a functional coating and another portion of the antibiotic is without a functional coating.

The secondary reference, Burnside, is similarly silent as to any such an arrangement. The Office Action cites paragraphs [0021-0023] as being relevant to the claimed invention. However, rather than describing a composition including a drug with a functional coating and then that drug without a functional coating, Burnside describes:

- 1) an active ingredient with an immediate release coating; and
- 2) an active ingredient with an enteric release coating.

Thus, in contrast to the claimed invention which provides for the presence and the absence of a functional coating, Burnside describes a composition with a drug that always has a coating.

Accordingly, the proposed combination of references not only fails to adequately describe a formulation where a penem antibiotic is provided with an inorganic substance suitable to preclude the penem antibiotic from degradation, but the references do not describe a formulation having an active ingredient a portion of the antibiotic has a functional coating and another portion of the antibiotic is without a functional coating

Reconsideration and withdrawal of this rejection are therefore respectfully requested.

CONCLUSION

In view of the foregoing, the application is respectfully submitted to be in condition for allowance, and prompt favorable action thereon is earnestly solicited.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket No. 100598.53322US).

Respectfully submitted,

March 14, 2008

/Christopher T. McWhinney/

Christopher T. McWhinney
Registration No. 42,875

Jeffrey D. Sanok
Registration No. 32,169

CROWELL & MORING LLP
Intellectual Property Group
P.O. Box 14300
Washington, DC 20044-4300
Telephone No.: (202) 624-2500
Facsimile No.: (202) 628-8844
JDS:CTM (4933850)